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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,676	03/16/2004	Kenji Nakajima	Q80045	4734
23373	7590	04/06/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/800,676	Applicant(s) NAKAJIMA ET AL.	
	Examiner Melanie Yu	Art Unit 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 20 January 2006.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-8 is/are rejected.

7) ☒ Claim(s) 9-16 is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All    b) ☐ Some    c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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### **DETAILED ACTION**

1. Applicant's amendment submitted 20 January 2006 has been entered. Claims 1-4 are currently amended. Claims 1-16 are pending in this application. Claims 9-16 have been withdrawn from consideration.

#### ***Withdrawn Rejections***

2. Previous rejections under 35 USC 112, second paragraph, 35 USC 102(b) and 35 USC 103(a) have been withdrawn in light of applicant's arguments.

#### ***Claim Objections***

3. Claims 9-16 are objected to because of the following informalities: status identifiers are required for all claims. Applicant is required to list claims 9-16 and their status, either withdrawn or canceled on the claims sheet. For the purposes of this office action, claims are treated as withdrawn. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 2, 4, 6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Claim 2 recites “the first layer, the second layer and the signal absorbing layer present below the base plate outside of the adsorptive regions”. The original specification fails to provide sufficient support for a first and second layer outside of an adsorptive region wherein a signal-absorbing layer is present. It is noted that the original specification teaches a first and second layer of porous material being outside the adsorptive regions prior to filling the adsorptive regions at page 32, line 15-page 33-line 4. However, the disclosure fails to provide support for the first and second layer being both outside and inside the adsorptive regions or a signal absorbing layer present outside the adsorptive regions when the first and second layer are present outside of the adsorptive region.

5. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “each of the adsorptive regions comprising a first layer and a second layer”. It is unclear whether the first and second layer must be layers of porous adsorptive material or whether the adsorptive region comprises a second material in addition to the porous material that has a first and second layer.

Claim 2 recites that the first and second layer are in one region are connected with a first and second layer corresponding to an adjacent region at one surface of the base plate. It is unclear whether the first and second layer may be connected through the base plate, or whether the first and second layers of one region must directly be connected with the first and second layers of another region. It is unclear how porous material filled in a plurality of physically separate holes, wherein the porous material is not placed anywhere outside the holes, would be

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capable of being connected with a first and second layer in another region unless the first and second layer of two separate holes are connected through the base plate.

Regarding claim 2, it is further unclear how the first and second layer are present below the base plate outside of the adsorptive regions, when each of the adsorptive regions comprises a first layer and a second layer. It is vague as to how the first and the second layers could be present both within the adsorptive region and below the base plate outside of the adsorptive regions.

With respect to claims 5-8, the term “constituting” is vague because it is unclear whether the base plate must be consisting of a material having radiation/light attenuating properties or whether the base plate must merely comprise a material having radiation/light attenuating properties.

***Claim Rejections - 35 USC § 103***

6. Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (US 2002/0094533) in view of Ogawa (US 6,492,119).

Hess et al. teach an analysis unit comprising: a base plate, which has a plurality of holes (plates have through-holes, par. 10-11); a porous adsorptive material which is filled in each of the plurality of the holes of the base plate and forms each of a plurality of adsorptive regions (through-holes contain porous material, par. 11, 15), but fail to teach the adsorptive regions comprising a first and second layer.

Ogawa teaches a first porous layer and a second porous layer wherein the first layer has a mean pore diameter that is larger (2a, Fig. 2; col. 2, lines 53-57) than a mean pore diameter of

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the second layer (2b, Fig. 2; col. 2, lines 57-59), in order to provide an array that does not suffer from bending and creasing which adversely affects analytic operations.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the porous material in the adsorptive region of the analysis unit of Hess et al., a first porous layer and a second porous layer wherein the first layer has a mean pore diameter larger than a mean pore diameter of the second layer as taught by Ogawa, in order to provide efficient application and immobilization of probes to the porous material in the through-hole because the solvent comprising the probe is quickly introduced toward the bottom of the hole.

With respect to claim 3, Ogawa teaches a small and large mean pore diameter size which encompasses a ratio of the mean pore diameter of the second layer to the mean pore diameter of the first layer being at most 0.7 (small mean pore diameter is between 0.1 and 1.0  $\mu\text{m}$ , col. 5, lines 19-22; large mean pore diameter is between 1.0 and 200  $\mu\text{m}$ ; col. 7, lines 8-26 describe a small mean pore diameter of 0.2  $\mu\text{m}$  and a large mean pore diameter of 10  $\mu\text{m}$ , therefore if the large mean pore diameter is taken as 1, the small mean pore diameter is 0.02, which encompasses the recited at most 0.7).

Regarding claims 5 and 7, Hess et al. teach the base plate constituted of a material having radiation and/or light attenuating properties (base plate coated with copper, gold or silver, which produces a light attenuating substrate, par. 16; base plate may be ceramic, par. 13; base plate may alternatively be made of PMMA, polystyrene or epoxy resins, par. 19).

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7. Claims 2, 4, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (US 2002/0094533) in view of Ogawa (US 6,492,119), as applied to claim 1, further in view of Ogura (US 2002/0061534).

Hess et al. in view of Ogawa, as applied to claim 1, teach a biochemical analysis unit comprising a first and second porous layer, wherein the first and second layers of the adsorptive regions is connected with a first and second layer corresponding to an adjacent one of the adsorptive regions (Hess et al. teach porous material in each of a plurality of through holes, par. 11, 15; when porous layers of Ogawa are substituted for the porous material of Hess et al., the first and second porous layers are connected through the base plate, Hess et al. Fig. 9, holes are adjacent to each other and porous material is connected through base plate material), but fail to teach a signal absorbing layer for absorbing a signal.

Ogura teaches a signal absorbing layer for absorbing a signal under a base plate (light absorbing materials are added to substrate par. 110; 11, Fig. 4 and 5, is a layer on the base plate 1, par. 247-248 and has light attenuating properties, therefore the support, 11, can have light absorbing materials in order to enhance light attenuating), in order to enhance light attenuating properties.

Therefore it would have been obvious to include in the biochemical analysis unit of Hess et al. in view of Ogawa, a signal absorbing layer for absorbing a signal under a base plate as taught by Ogura, in order to prevent noise caused by scattering during irradiation and to enhance detection signals. By placing the signal absorbing layer below the base plate of Hess et al. in view of Ogawa, the signal absorbing layer is present below the adsorptive regions that contain

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the first and second layers, as described above, and are therefore present below the first and second layers in the adsorptive regions.

With respect to claim 4, Ogawa, as applied to claim 3, teaches a small and large mean pore diameter size which encompasses a ratio of the mean pore diameter of the second layer to the mean pore diameter of the first layer being at most 0.7.

Regarding claims 6 and 8, Hess et al., as applied to claim 5, teach a base plate constituted of a material having light attenuating properties.

#### ***Response to Arguments***

8. Applicant's arguments, see pages 5-7, filed 20 January 2006, with respect to rejection of claims 1-8 have been fully considered and are persuasive, but are moot in view of the new ground(s) of rejection. Previous rejections of claims 1-8 have been withdrawn.

#### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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02/21/08